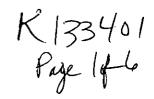
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SEEMENS

Traditional 510(k) Submission / Bundling 510(k) for: syngo.MR Post-Processing Software (Version SMRVA16B)

510(k) Summary:

syngo.MR Neurology, syngo.MR Oncology, syngo.MR BreVis and syngo.mMR General

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Device Act 1990 and 21 CFR § 807.92.

Date of Summary Preparation: November 5, 2013

I. General Information

Importer / Distributor

Siemens Medical Solutions USA, Inc.

51 Valley Stream Pkwy

Mail Code D02

Malvern, PA 19355, USA

Registration Number:

2240869

Manufacturer

Siemens AG Medical Solutions Henkestrasse 127

D-91052 Erlangen, Germany

Registration Number:

3002808157

Contact Person

Nadia Sookdeo

Regulatory Affairs Technical Specialist Siemens Medical Solutions USA, Inc.

51 Valley Stream Pkwy

Mail Code D02

Malvern, PA 19355, USA Phone: (610) 448-4918 Fax: (610) 448-1787

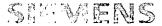
Email: nadia.sookdeo@siemens.com



Traditional 510(k) Submission / Bundling 510(k) for: syngo.MR Post-Processing Software (Version SMRVA16B)

Device Name and Classification

| Device Name and Cl | assincation | | | | |
|--------------------------|---|--|--|--|--|
| Data | Details | | | | |
| Trade name / | syngo.MR Neurology | | | | |
| Device Proprietary | | | | | |
| Name: | syngo.MR Neurology covers single and engine applications: | | | | |
| | syngo.MR Neuro Perfusion syngo.MR Neuro Perfusion Mismatch | | | | |
| | | | | | |
| | syngo.MR Neuro fMRI | | | | |
| | syngo.MR Tractography | | | | |
| | syngo.MR Neuro Perfusion Engine | | | | |
| | syngo.MR Neuro 3D Engine | | | | |
| | syngo.MR Oncology | | | | |
| | syngo.MR Oncology covers single and engine applications: • syngo.MR Onco | | | | |
| | syngo.MR 3D Lesion Segmentation | | | | |
| | • syngo.MR Tissue4D | | | | |
| | • syngo.MR Onco Engine | | | | |
| | syngo.MR BreVis syngo.MR BreVis is available as single application. | | | | |
| | syngo.mMR General | | | | |
| | syngo.mMR General is available as single application. | | | | |
| Classification | Regulation Description: | | | | |
| Name: | - Picture Archiving and Communication System (PACS) | | | | |
| Classification Panel: | Radiology | | | | |
| Device | Class II devices | | | | |
| Classification: | | | | | |
| Regulation number: | 21 CFR § 892.2050 | | | | |
| Product Code: | Primary: LLZ, Secondary: LNH | | | | |



II. Safety and Effectiveness Information Supporting Substantial Equivalence

Intended Use

The software comprising the *syngo*.MR post-processing applications are post-processing software / applications to be used for viewing and evaluating the designated images provided by a magnetic resonance diagnostic device. All of the software applications comprising the *syngo*.MR post-processing applications have their own indications for use.

syngo.MR Neurology is a syngo based post-processing software for viewing, manipulating, and evaluating MR neurological images.

syngo.MR Oncology is a syngo based post-processing software for viewing, manipulating, and evaluating MR oncological images.

syngo.mMR General is a *syngo* based post-processing software for viewing, manipulating, and evaluating MR, PET and MR-PET images.

syngo.MR BreVis is a software package intended for use in viewing and analyzing magnetic resonance imaging (MRI) studies. syngo.MR BreVis supports evaluation of dynamic MR data. Depending on the region of interest, contrast agents may or may not be used.

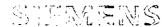
syngo.MR BreVis automatically registers serial patient motion to minimize the impact of patient motion and visualizes different enhancement characteristics in those areas that are within the scope of the indications for use of MRI FDA approved contrast agents (parametric image maps). Furthermore, it performs other user-defined post-processing functions such as image subtractions, multiplanar reformats and maximum intensity projections. The resulting information can be displayed in a variety of formats, including a parametric image overlaid onto the source image. syngo.MR BreVis can also be used to provide measurements of the diameters, areas and volumes.

Furthermore syngo.MR BreVis can evaluate the uptake characteristics of segmented tissues that are within the scope of the indications for use of MRI FDA approved contrast agents. syngo.MR BreVis is optimized for viewing breast MR studies, and it also displays images from a number of other imaging modalities, like digitized mammographic images.

The images by other imaging modalities displayed with *syngo*.MR BreVis must not be used for primary diagnostic interpretation. *syngo*.MR BreVis also includes the option to add annotations based on the American College of Radiology's BI RADS (Breast Imaging Reporting and Data System). When interpreted by a skilled physician, *syngo*.MR BreVis provides information that may be useful in diagnosis. Patient management decisions should not be made based solely on the results of *syngo*.MR BreVis analysis.

Device Description

syngo.MR Neurology, syngo.MR Oncology, syngo.MR BreVis and syngo.mMR General are post-processing software / applications to be used for viewing and evaluating MR images provided by a magnetic resonance diagnostic device. syngo.MR Neurology, syngo.MR Oncology, syngo.MR BreVis and syngo.mMR General are syngo.via-based software that enable structured evaluation of MR images.



syngo.MR Neurology, syngo.MR Oncology, syngo.MR BreVis and syngo.mMR General comprise the following (please refer to **Table 1**).

Table 1: syngo.MR General, syngo.MR Cardiology and syngo.MR Vascular and their content

| content | |
|----------------------|--|
| Medical device / | covered single and engines applications |
| post-processing | · |
| application | |
| syngo.MR | syngo.MR Neuro Perfusion |
| Neurology | allows the visualization of temporal variations in the dynamic susceptibility time series of MR datasets. |
| | syngo.MR Neuro Perfusion Mismatch calculates the difference between the DWI lesion (diffusion ROI) and the PWI lesion (perfusion ROI) areas. |
| | syngo.MR Neuro fMRI is a workflow-oriented visualization package for BOLD fMRI. It enables the visualization of task-related areas of activation overlaid onto 2D or 3D anatomical datasets, providing the spatial correspondence of BOLD results. |
| | syngo.MR Tractography (NEW) allows assessment of central nervous system structures through utilitzing 3D tractographic data derived from Diffusion Tensor Imaging. |
| | syngo.MR Neuro Perfusion Engine Contains: - syngo.MR Neuro Perfusion - syngo.MR Neuro Perfusion Mismatch |
| | syngo.MR Neuro 3D Engine Contains: - syngo.MR Neuro fMRI - syngo.MR Tractography |
| syngo.MR Oncology | syngo.MR Onco is a image viewing, processing and reading software that allows for oncological MR image evaluation in a structured way. |
| | syngo.MR 3D Lesion Segmentation provides convenient volumetric evaluation of lesions and/or other structure of interest as well as a particularly useful tool for oncology applications. |

Table 1: syngo.MR General, syngo.MR Cardiology and syngo.MR Vascular and their content

| Medical device / | covered single and engines applications | | |
|-----------------------------|---|--|--|
| post-processing application | , , | | |
| | | | |
| | syngo.MR Onco Engine contains: - syngo.MR Onco - syngo.MR 3D Lesion Segmentation | | |
| syngo.MR BreVis | syngo.MR BreVis (NEW) is a software package intended for use in viewing and analyzing magnetic resonance imaging (MRI) studies. | | |
| syngo.mMR General | syngo.mMR General (NEW) is a syngo based post-processing software for viewing, manipulating and evaluating MR, PET and MR-PET images. | | |

General Safety and Effectiveness Concerns

Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner.

Product risk management is accomplished through a process in compliance with ISO 14971:2009 to identify and provide mitigation to potential hazards in a risk analysis beginning early in the design phase and continuing throughout the development of the product. These risks are controlled via measures realized in software development, SW testing and product labeling. To minimize risks, Siemens adheres to recognized and established industry practices and standards. Furthermore, the operators are healthcare professionals familiar with and responsible for the evaluating and post-processing of magnetic resonance images.

syngo.MR Neurology, syngo.MR Oncology, syngo.MR BreVis and syngo.mMR General conform to the applicable FDA recognized and international IEC, ISO and NEMA standards with regards to performance and safety as recommended by the respective MR FDA Guidance Document.

Substantial Equivalence

syngo.MR Neurology, syngo.MR Oncology, syngo.MR BreVis and syngo.mMR General are substantially equivalent to the following current legally marketed devices (please refer to **Table 2**):

K133401 Page 646

SEEMENS

<u>Traditional 510(k) Submission / Bundling 510(k) for:</u>
<u>syngo.MR Post-Processing Software (Version SMRVA16B)</u>

Table 2: Predicate devices for syngo.MR Neurology, syngo.MR Oncology, syngo.MR BreVis and syngo.mMR General

| Predicate Device Name | FDA Clearance Number | FDA Clearance Date | Product Code |
|--|----------------------------|-----------------------|--------------|
| syngo.MR Post-Processing Software Version SMRVA16A | K130749 | August 20, 2013 | LLZ LNH |

Conclusion as to Substantial Equivalence

The syngo.MR post-processing applications are intended for similar indications as cleared in the predicate devices, as previously noted.

In summary, Siemens is of the opinion that the *syngo.MR* post-processing applications do not raise new questions of safety or effectiveness and are substantially equivalent to the currently marketed device *syngo.*MR Post-Processing Software Version SMRVA16A (K130749 cleared on August 20, 2013).

There are minor changes to the indications for use for the subject devices, compared to that of the predicate device *syngo*.MR Post-Processing Software Version SMRVA16A. The differences between the subject devices and the predicate device include the aforementioned improved changes, adaption to the updated *syngo*.via basis platform and other enhancements. The differences give the device greater capabilities than the predicate device, but have same technological characteristics and functionalities as the predicate device, and do not introduce any new issues of safety or effectiveness.

Therefore, Siemens believes that the subject devices, the *syngo.MR* post-processing applications, are substantially equivalent to the predicate device listed above.



Food and Drug Administration 10903 New Hampshire Avenue Document Control Center – WO66-G609 Silver Spring, MD 20993-0002

Siemens Medical Solutions USA, Inc. % Ms. Nadia Sookdeo Regulatory Affairs Technical Specialist 51 Valley Stream Parkway MALVERN PA 19355

March 11, 2014

Re: K133401

Trade/Device Name: syngo.MR Neurology, syngo.MR Oncology, syngo.MR BreVis,

syngo.mMR General

Regulation Number: 21 CFR 892.2050

Regulation Name: Picture archiving and communications system

Regulatory Class: Il Product Code: LLZ, LNH Dated: February 12, 2014 Received: February 18, 2014

Dear Ms. Sookdeo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its tollfree number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Muchal D. OHara

Janine M. Morris Director, Division of Radiological Health Office of In Vitro Diagnostics and Radiological Health Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

Form Approved: OMB No. 0910-0120 Expiration Date: December 31, 2013

| Indications for Use | See PRA Stalement on last page. |
|--|---|
| 510(k) Number (if known) | |
| K133401 | |
| Device Name syngo.MR Neurology, syngo.MR Oncology, syngo.MR BreVis and syngo.mMR General | al |
| Indications for Use (Describe) The software comprising the syngo.MR post-processing applications are post-processiny viewing and evaluating the designated images provided by a magnetic resonance diagnocomprising the syngo.MR post-processing applications have their own indications for users. | stic device. All of the software applications |
| syngo.MR Neurology is a syngo based post-processing software for viewing, manipulat | ing, and evaluating MR neurological images. |
| syngo.MR Oncology is a syngo based post-processing software for viewing, manipulati | ng, and evaluating MR oncological images. |
| syngo.mMR General is a syngo based post-processing software for viewing, manipulating images. | ng, and evaluating MR, PET and MR-PET |
| syngo.MR BreVis is a software package intended for use in viewing and analyzing mag syngo.MR BreVis supports evaluation of dynamic MR data. Depending on the region of | netic resonance imaging (MRI) studies. Finterest, contrast agents may or may not be |
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| syngo.MR BreVis also includes the option to add annotations based on the American Colinaging Reporting and Data System). When interpreted by a skilled physician, syngo.Museful in diagnosis. Patient management decisions should not be made based solely on the syngo. | IR BreVis provides information that may be |
| Type of Use (Select one or both, as applicable) | |
| ✓ Prescription Use (Part 21 CFR 801 Subpart D) | Counter Use (21 CFR 801 Subpart C) |
| PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON A | SEPARATE PAGE IF NEEDED. |
| FOR FDA USE ONLY | |
| Concurrence of Center for Devices and Radiological Health (CDRH) (Signature) | |
| Michael D. C | Hara |
| | |